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Via ECF

The Honorable Valerie Figueredo
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street
New York, NY 10007-1312

Re: Nonparty Northwell Health's Motions to Modify in *Brian Joseph Gref v. American International Industries, et al.*, No. 1:20-cv-05589-GBD-VF

Dear Judge Figueredo,

As allowed by your Honor during the February 8, 2023 oral argument on Northwell Health, Inc.'s ("Northwell") Motions to Modify nonparty subpoenas ("Nonparty Subpoenas") served on Northwell by Defendants American International Industries ("AII") and Whittaker, Clark and Daniels, Inc. ("WCD") (collectively, "Subpoenaing Defendants"), Northwell respectfully submits this consolidated reply to address Subpoenaing Defendants' supplemental response briefs.

Northwell is not a party to this case. The 33 individuals that Dr. Moline and her co-authors studied are not parties to this case. And Subpoenaing Defendants waited more than two years after this case was filed—and after Dr. Moline had already been deposed—to subpoena Northwell. They seek to use the subpoena power to force nonparty Northwell to re-identify the 33 anonymous individuals described in Dr. Moline's article (the "Article") and thereby expose their protected health information (PHI). Upon receiving the Nonparty Subpoenas, Northwell objected and moved to modify them under Rule 45. Now, Subpoenaing Defendants want this Court to be the first tribunal to order a nonparty hospital to re-identify the subjects of a peer-reviewed, scholarly research study, thereby revealing the subjects' PHI.

Such an order would unduly burden nonparty Northwell by forcing it to publicly violate federal regulations, its own policies, and its core values, and by inflicting a chilling effect on its future medical research. What is worse, re-identifying the individuals will make them stars of future cross-examinations in asbestos cases around the country. And for what? Because Subpoenaing Defendants think that if they probe deeply enough into these individuals' backgrounds, they *might* be able to more robustly cross-examine Dr. Moline in future litigations, notwithstanding the ample fodder they already possess to do so, as featured prominently in their briefing. This is simply not an

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adequate justification for imposing substantial burdens on a nonparty hospital and exposing the subjects of the Article to repeated disclosure of their PHI in cases across the country.

This Court can protect Northwell and the subjects of the Article by employing either of the two Rule 45 pathways articulated in Northwell’s briefing, oral argument, and supplemental letter:

- **Pathway 1**: Ruling that the Nonparty Subpoenas require disclosure of privileged or other protected matters; or
- **Pathway 2**: Ruling that the Nonparty Subpoenas subject Northwell to undue burden.

Subpoenaing Defendants hope that by filing a voluminous and wide-ranging supplemental brief, they can overwhelm the Court with new issues and arguments—many not raised in their initial briefing or at oral argument—such that it will lose sight of these two pathways, the unprecedented nature of Subpoenaing Defendants’ demands, and the harm re-identifying the subjects of the Article would inflict, both on Northwell and the subjects.

The factual and legal errors in Subpoenaing Defendants’ 30 pages of supplemental briefing are too numerous to describe individually. Instead, Northwell offers the following points in reply:

Pathway 1

- Subpoenaing Defendants mischaracterize the information at issue. Northwell’s motions are not about—and Northwell is not in possession of—lists of “names of lawsuits” or “names of litigants,” “case list[s],” or a “spreadsheet identifying the 33 lawsuits.” Instead, Northwell’s motions seek to protect the identities of the individuals whose de-identified PHI appears in the Article because identifying them necessarily re-identifies the PHI currently cloaked by anonymity.¹
- In the course of conducting medical research, Northwell—indisputably a covered entity²—

¹ Northwell is permitted to use PHI in this fashion so long as it is de-identified. *See* 45 C.F.R. § 164.514.

² It is beyond dispute that Northwell, the largest hospital system in New York, is a covered entity under HIPAA. *See* 45 C.F.R. § 160.103. Further, the Northwell “HIPAA and State Privacy Breach Notifications” policy that AII attached to its supplemental brief underscores that Northwell is a covered entity. (ECF 319-21 (“In compliance with the HIPAA Privacy Rule, violations of this policy will be subject to disciplinary action”)) The same is true for the blank Northwell “Authorization for Release of Health Information” form attached to Subpoenaing Defendants’ supplemental brief as Exhibit Y. (ECF 319-26)

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received the names and PHI^{3,4} of 33 individuals with malignant mesothelioma. Those individuals have not authorized Northwell to disclose their identities or PHI.⁵ Thus, HIPAA prohibits Northwell from doing so.⁶ There is no public disclosure exception to this prohibition. And it applies regardless of whether Dr. Moline or Northwell had a physician-patient relationship with any of the individuals.

- Thus, the fact that the individuals were plaintiffs years ago and that Northwell studied certain information derived from litigation materials is irrelevant to the HIPAA analysis (Pathway 1), and does little if anything to undermine Northwell's undue burden argument (Pathway 2).
- Providing examples of HIPAA authorizations is not a HIPAA violation because the authorizations do not contain PHI.⁷ Providing a HIPAA authorization with a name on it (revealing no PHI), is distinct from providing the names of the patients whose anonymized health information appears in the Article (thereby revealing PHI in violation of HIPAA).
- The language in the example HIPAA authorizations acknowledging the risk of "re-disclosure by the recipient" of the authorization is inapposite.⁸ Northwell never received HIPAA authorizations from the patients at issue; thus, none of the individuals consented to the risk that Northwell might re-disclose their PHI.
- Judge Osteen did not have the benefit of the complete record in this case, including a copy of Northwell's Federal Wide Assurance (FWA); thus, his dicta in footnote 8 of his order in *Bell* reflects a misunderstanding of Northwell's obligations under its FWA. At any rate, because it is

³ See 45 C.F.R. § 160.103 (defining "protected health information" as "individually identifiable health information," which in turn is defined as "information that is a subset of health information including demographic information collected from an individual, and: (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.").

⁴ The Northwell "HIPAA and State Privacy Breach Notifications" policy that AII attached to its brief defines PHI as "[a]ny oral, written, or electronic individually identifiable health information. PHI is information created or received by Northwell that (i) may relate to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the payment for the provision of health care to an individual; and (ii) identifies the individual who is the subject or based on which there is a reasonable basis to believe that the individual who is the subject can be identified." (ECF 319-21)

⁵ Again, Northwell is permitted to use PHI for research purposes so long as it is de-identified. See 45 C.F.R. § 164.514.

⁶ 45 C.F.R. § 164.502(a) ("A covered entity . . . may not use or disclose [PHI], except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.")).

⁷ As indicated in the detailed table of exhibits in ECF 314, Ms. Jackson's release was selected as one of the examples because she was featured prominently in AII's original response brief. (ECF 279 p. 25; ECF 314 p. 4, rows R and S)

⁸ The blank Northwell "Authorization for Release of Health Information" form attached to Defendants' supplemental brief as Exhibit Y contains similar language. (ECF 319-26)

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dicta, it has no precedential effect. If this holding had comprised part of Judge Osteen's holding, Northwell would have challenged it. But, alas, this issue was not a part of the court's holding.

Pathway 2: Undue Burden

- Subpoenaing Defendants' supplemental briefs largely ignore Northwell's burden argument (Pathway 2).
- Pathway 2 is the framework utilized by the federal courts in *In re American Tobacco Co.*, 880 F.2d 1520 (2d Cir. 1989) and *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 249 F.R.D. 8, 13-14 (D. Mass. 2008). It is also the framework the Eastern District of Virginia used to quash a similar nonparty subpoena and sanction AII in this same litigation.⁹
- Subpoenaing Defendants repeatedly cite to *American Tobacco*, a Second Circuit case wherein the identities of the subjects remained redacted.¹⁰ Similarly, the courts in *Deitchman v. ER Squibb*¹¹ and *Lampshire v. Proctor & Gamble Co.*¹² protected the identities of the subjects at issue. Indeed, this Court would be the first federal court in the country to order a nonparty hospital to reveal the identities of individuals studied in a scholarly research article (aside from *Bell*, which involved unique circumstances simply not present here).

In sum, Defendants' shotgun blast of arguments—ranging from withdrawn testimonial subpoenas¹³ to accusations of bad faith¹⁴—don't move the needle. The core of the dispute is unchanged and the two pathways for resolving it remain viable. Northwell moved to modify the Nonparty Subpoenas because disclosing the names of the 33 individuals would re-identify all of the anonymous PHI in the Article. This would be unfair to those individuals, who are strangers to this case. It would violate Northwell's core values as a hospital and its internal policies. It would violate federal regulations

⁹ *Peninsula Pathology Associates*, No. 4:22-mc-1 (E.D. Va. Dec. 23, 2022) (sanctioning AII for serving a similar nonparty subpoena, which the Court held was unduly burdensome).

¹⁰ See generally *In re American Tobacco Co.*, 880 F.2d 1520 (2d Cir. 1989) (upholding extensive redactions "to protect the anonymity of the study participants").

¹¹ *Deitchman v. ER Squibb*, 740 F.2d 556, 565 (7th. Cir. 1984) ("[W]e do not believe that this case calls for release of identifying information . . .").

¹² *Lampshire v. Proctor & Gamble Co.*, 94 F.R.D. 58 (GAND 1982) ("The court . . . concludes that the personal identifying information about subjects in the CDC studies . . . should be redacted from all produced documents.").

¹³ The additional subpoenas appended to AII's supplemental brief as Exhibits Q and R were procedurally improper, an abuse of process, and infeasible given their timing. Additionally, the subpoena to Northwell demanded that Northwell produce for testimony "the person most knowledgeable" without specifying the subject of the knowledge - most knowledgeable about what? When confronted with these defects—and the prospect of having to defend the subpoenas in court—AII voluntarily withdrew them. See **Exhibit A**.

¹⁴ "[A]voiding response to the instant subpoenas suggests that the claims of confidentiality in the instant motion are not made in good faith." (ECF 320 p 4)

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and inflict a chilling effect on future medical research. This Court should not be the first federal court to inflict these burdens on a nonparty hospital, especially not after Subpoenaing Defendants waited more than two years to serve the Nonparty Subpoenas.

Best regards,

/s/ Nathan A. Huff

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